

## REMARKS

### I. Status of the claims

Claims 1-3, 17-19, and 21-22 are pending.

Claims 4-16, and 20 are withdrawn reserving the right to prosecute them in continuing or divisional applications.

### II. Claims 1-3, 17-19, and 21-22 Satisfy 35 U.S.C. § 112 Second Paragraph

#### Requirements

On page 2 of the Action, the examiner rejected claims 1-3, 17-19, and 21-22 under 35 U.S.C. § 112 second paragraph as being indefinite. The examiner believes that the terms “comparative protein”, “antigenic profile”, and “administered to the cells of an individual” are indefinite.

However, “**comparative proteins**” are extensively defined in the specification *e.g.*, on page 2, lines 35-36 to page 3, lines 1-7, and page 12, lines 29-31, the specification describes “comparative proteins” as non-targeted and non-specific proteins that show no more than 50% homology with the targeted protein as determined by computer-aided analysis. In addition, FIGS. 2a-2b of the specification (page 10, lines 31-35; page 11, lines 1-15) illustrate the alignment of the flagellar sheath adhesion protein of *H. pylori* with sequences of two comparative proteins pspA and Lp1 from *S. pneumoniae* and *M. hominis* respectively. Furthermore, FIGS. 3-5 show results from candidate target peptides that were selected based on the comparison of amino acid sequences between the target peptides and the peptides from the comparative proteins (page 13, lines 3-12 of the specification). Therefore, the specification adequately describes “comparative proteins” and provides examples of such comparative proteins.

Regarding “**antigenic profile**”, on page 5, lines 33-44, the specification discloses “an antigenic profile which elicits a highly specific, antibody-reactive or an immune cell reactive immune response” as part of the structure of “suitable peptides” for practice of the invention. In addition, on page 4, lines 36-44, the specification discloses a method to determine immunospecificity of the synthetic peptides by comparing immunoassay results from disease-positive and disease-negative biological fluids. In light of the disclosure in the specification and the general usage of the term in the art [for example: Kivela T. 1992 Antigenic profile of the human lacrimal gland. *J Histochem Cytochem.* 40(5):629-42;], the term “antigenic profile” is not indefinite.

Regarding “**administered to the cells of an individual**”, claim 20 refers to a non-elected claim. This rejection will be addressed in a continuing application if repeated.

### **III. Barry *et al.* Do Not Anticipate claims 1-3, and 17 because Barry Does Not Teach All the Claim Elements**

The examiner believes Barry *et al.* anticipate a peptide of claim 1 and its dependent claims. The goal of Barry *et al.* was:

Using single amino acid substitution mutagenesis, we have now determined that Asp21 and Glu22, but not Thr25, were crucial for full IL-3 activity. (Abstract)

Claims 1-3 and 17 refer to peptides and immunogenic compositions that produce a disease or condition specific immune response in a host. Barry does not teach such peptides or immunogenic compositions.

Barry *et al.* report that IL-3 is a hematopoietic cytokine (page 8488, right column)—not an immunogenic peptide. IL-3 is 133 amino acids in length, exceeding the limits of claim 1. Also, Barry *et al.* reports that IL-3 is a glycoprotein that stimulates cell adhesion, cell migration and mediates other pleiotropic effects (page 8488, left column), not that IL-3 elicit a specific immune response as in claim 1.

On page 3 of the Action, the examiner stated “IL-3 has been shown capable of eliciting **various immunological functions,.....**” (*emphasis added*). In the laundry list of the immunological functions provided by the examiner, there is no indication that the peptide “elicits an immune response specific for the target protein” as in claim 1.

Barry *et al.* did not teach “comparative proteins” as defined in the present disclosure. Barry aligned IL-3 with segments of IL-5 and GM-CSF merely to predict a helical structure for IL-3. On page 8489, under “Results” section, the authors state:

*Predicted Helix A of IL-3*—We have **modeled the first helix of human IL-3** on the known structure of GM-CSF (11). Sequence alignment **suggested a strong structural similarity** exists between the first helices GM-CSF, IL-3, and Il-5. (*emphasis added*)

Barry does not satisfy the legal criteria for anticipation. The sequence alignment was not performed to identify immunogenic peptide regions or define comparative protein. In addition, there was no teaching in Barry, that the aligned peptides were immunogenic. Barry does not compare immunogenic regions of a “target” protein to “comparative” proteins as in claim 1. Barry *et al.*, merely predict the functionality of IL-3 in receptor binding based on known helical structures. Therefore, Barry *et al.* does not anticipate claim 1-3, and 17, which are to peptides and immunogenic compositions that elicit specific immune response in specific diseases or condition.

To anticipate a claim, a reference **must disclose every element of the challenged claim** and enable one skilled in the art to make the anticipating subject matter...

PPG Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996).

It is elementary that an anticipation rejection requires a showing that **each limitation of a claim must be found in a single reference**, practice, or device.

*In re Donohue*, 766 F.2d 531 (Fed. Cir. 1985).

To serve as an anticipating reference, **the reference must enable that which it is asserted to anticipate.** "A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled."

*Elan Pharm. v. Mayo Found.*, 346 F.3d 1051 (Fed. Cir. 2003). (*emphasis added*)

#### **IV. Regenmortel Does Not Anticipate Claims 1-3, 17, and 21**

On page 3 of the Action, the examiner states “Regenmortel disclose mimotopes peptides where those peptides can bind to the target molecules but do not share sequence similarity with the target protein on the cell surface”.

Based on the examiner’s interpretation of Regenmortel, claim 1 is not anticipated. Regenmortel is a review article. An immunogenic peptide of claim 1 does **not** bind to its target, it comes from a target. In addition, an immunogenic peptide of claim 1 by definition **does** share homology with the target protein and shows no more than 50% homology only with the comparative proteins—not the target proteins.

Regenmortel merely reports the possible use of synthetic mimotopes (no sequence homology but possible structural similarity) in diagnostics to determine viral infection. Regenmortel reports

However, because the use of viral antigenic probes entails handling infectious materials, researchers are replacing those materials with synthetic peptides to avoid potential hazard.

(page 332, left column)

Regenmortel further reports

Such molecular libraries often contain peptides that bind to the appropriate antibodies but **show no sequence similarity with the viral proteins** that the peptides correctly mimic in a functional sense.

(page 334, right column). (emphasis added)

Regenmortel does not anticipate claims 1-3, 17, and 21.

It is elementary that an anticipation rejection requires a showing that **each limitation of a claim must be found in a single reference**, practice, or device.

(emphasis provided) *In re Donohue*, 766 F.2d 531 (Fed. Cir. 1985)

#### **V. A Prima Facie Case of Obviousness is Not Established for Claims 18-19, and 22**

On pages 4-5 of the Action, the examiner argues that Regenmortel in view of Hasegawa (US Pat 4606857) renders claims 18-19 obvious.

The examiner admits Regenmortel does not teach immunogenic peptides as in claim 1, and uses Hasegawa to produce an adjuvant.

Hasegawa merely teaches adjuvants. There is no teaching or suggestion to combine Regenmortel and Hasegawa. Even if Regenmortel and Hasegawa were combined, the combination does not render claims 18-19 obvious because neither Regenmortel nor Hasegawa does not teach or suggest an immunogenic peptide that fits the description of claim 1.

On page 5 of the Action, the examiner believes that Regenmortel in view of Tu (US Pat 5674483) renders claim 22 obvious. Tu merely teaches a method of administering IL-12 to reduce inflammation. IL-12 is a “heterodimeric cytokine” exceeding the limits of claim 1 (Howard *et al.* Chap. 20, Fundamental Immunology)

In *Nursery Supplies*, the court held:

**One cannot simply backtrack from the invention to find a connection** to the prior art. Hindsight must be avoided. See *W.L. Gore and Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983).

Rather, **one must start with the prior art and find some suggestion or motivation either in a single reference** to modify it to produce the claimed invention, or some suggestion or motivation in a group of references to combine them to produce the claimed invention. *Nursery Supplies v. Lerio Corp.*, 45 U.S.P.Q.2d (BNA) 1332 (M.D. Pa. Sept. 19, 1997). (*emphasis added*).

There is no teaching or suggestion to combine Regenmortel and Tu. Even if Regenmortel and Tu were properly combined, the combination does not render claim 22 obvious because Regenmortel does not teach or suggest an immunogenic peptide that fits the description of claim 1, and TU only teaches IL-12.

It is to be noted, however, that citing references which **merely indicate that isolated elements and/or features** recited in the claims are known **is not a sufficient basis** for concluding that the combination of claimed elements would have been obvious. *Ex parte Hiyamizu* (BPAI 1988) 10 P.Q. 2d 1393 (*emphasis added*).

Even if all of the elements of a claim are present in the prior art, the claim will not be obvious unless the prior art also contained, at the time the claim was filed, a motivation to combine prior art elements into the claimed invention. The conclusion that the prior art contained a motivation to combine is a conclusion of fact. *Scimed Life Sys. v. Johnson & Johnson*, 2004 U.S. App. LEXIS 510.

Obviousness requires **a suggestion of all limitations** in a claim". *CFMT, Inc. v. Yieldup Int'l Corp.*, 2003 U.S. App. LEXIS 23072 (Fed. Cir. 2003) (*emphasis added*).

To properly combine two references to reach a conclusion of obviousness, there must be some teaching, suggestion or inference in either or both of the references, or knowledge generally available to one skilled in the art, which would have led one to combine the relevant teachings of the two references. *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc. et al.* (CAFC 1985) 776 F. 2d 281, 227 USPQ 657; *Ex parte Levengood, supra*. Both the suggestion to make the claimed composition or device or carry out the claimed process and the reasonable expectation of success must be founded in the prior art, not in applicant's disclosure. *In re Vaeck* (CAFC 1991) 947 F. 2d 488, 20 P.Q. 2d 1438. The references, viewed by themselves and not in retrospect, must suggest doing what applicant has done. *In re Shaffer* (CCPA 1956) 229 F. 2d 476, 108 USPQ 326; *In re Skoll* (CCPA 1975) 523 F. 2d 1392, 187 USPQ 481.

*In re Rouffet*, the court held

“To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court **requires the examiner to show a motivation to combine the references that create the case of obviousness**. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.” In *re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998). (*emphasis added*).

Therefore, Claims 18-19, and 22 are not obvious over Regenmortel in view of either Hasegawa or Tu.

#### VI. Conclusion and Summary

In view of the arguments presented herein, please allow all pending claims.

An interview is requested to resolve any remaining issues.

No fees are believed due at this time, however, please charge any additional deficiencies or credit any overpayments to deposit account number 12-0913 with reference to our attorney docket number (21417/92378).

Respectfully submitted,



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